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09/123,614	07/28/1998	LEE M. MIDDLEMAN	12032	5740

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EXAMINER	
RODRIGUEZ, CRIS LOIREN	
ART UNIT	PAPER NUMBER
3763	25

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/123,614	Applicant(s) MIDDLEMAN ET AL.	
	Examiner Cris L. Rodriguez	Art Unit 3763	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7-11,22,24-47 and 60-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-11,22,24-47 and 60-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2, 7-11, 22, 24-47, 60-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1, 28 and 38 are indefinite because it is not clear how the tubular element is anchored in the passageway if the anchoring members are the ones anchoring the deployment element. It seems that it limits the tubular element axial movement.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 11, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cathcart et al (US 5,681,347).

Cathcart discloses a device 10 comprising a tubular element 13 comprising a hollow tubular lumen, a deployment element (17,**20**) having an inner lumen, and a plurality of resilient anchoring members 24 attached to the distal end of the inner lumen (see fig. 4). Please note that the word "attached" means to join or connect. The word join is being used as "to put into close association or relationship" according to the Webster's II dictionary.

5. Claims 1, 2, 7, 10, 11, and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goldberg et al (US 5,152,777).

Goldberg discloses a device having a tubular element 70,72,74 with a hollow tubular lumen, a deployment element (stem 60,90) (also considered as the guide wire set forth in claims 7, 40 and 50) having a lumen 62, and a plurality of resilient anchoring members 32A-32F as claimed. The collar is reference numeral 38. In column 8 lines 23-66, it set forth that the deployment element(stem) has a lumen from proximal to distal end in order to introduce a guidewire or a marker solution into the body.

6. Claims 38-40, 44 and 45 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hayashi (5,910,144).

Hayashi discloses a prosthesis gripping system comprising a tubular element 20,26 comprising a hollow tubular lumen, a deployment element 50 (the guide wire set forth in claims 7, 40 and 50 is reference numeral 36), and a plurality of resilient anchoring members 40 as claimed. The collar is reference numeral 50.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over et al Cathcart et al in view of Hayman et al (5,267,960) and Abrams (5,492,119).

Cathcart discloses the invention substantially as claimed. However, Cathcart fails to disclose the anchoring members comprising spring steel or a pseudo elastic material such as nickel titanium alloy.

Hayman teaches an anchor 19 having arms 21 made of spring steel, and Abrams teaches a catheter apparatus comprising control wires having curved feet made of nitinol, which is a pseudo elastic material for anchoring purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Cathcart et al by providing the anchoring members with the materials of Abrams and Hayman as taught old and well known in the art for anchoring purposes.

9. Claims 8, 9, 26, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. in view of Abrams.

Goldberg discloses the invention substantially as claimed as discussed above. However, Goldberg fails to disclose the anchoring members being of a pseudo elastic material such as nickel titanium alloy, or the anchoring members having an oval cross-section.

Abrams teaches a catheter apparatus comprising control wires having curved feet for anchoring purposes, made of nitinol, which is a pseudo elastic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify

Goldberg by providing the anchoring members with the materials of Abrams as taught old and well known in the art for anchoring purposes. Also, the oval cross-section is an obvious variation from the circular cross-section.

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al in view of Lefebvre (US 5,938,683).

Goldberg discloses the invention substantially as claimed as discussed above. However, Goldberg fails to disclose the anchoring members having a substantially flat top portion.

Lefebvre teaches a filter (anchoring member) comprising a substantially flat top portion for anchoring in a blood vessel (see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg by providing the anchoring members with the substantially flat top portion as shown by Lefebvre to anchor the anchoring members to the passageway of a blood vessel and as an obvious design alternative.

11. Claims 24, 25, 28-30, 33-36, 60and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al in view of Hayashi.

Goldberg discloses a device having a tubular element 70,72,74 with a hollow tubular lumen, a deployment element 60,90,92 (also considered as the guide wire set forth in claims 7, 40 and 50), and a plurality of resilient anchoring members 32A-32F as claimed. The collar is reference numeral 38. However, Goldberg fails to disclose the anchoring members being attached within the wall of the deployment means inner lumen, or attached to the inner surface of the wall of the deployment means inner lumen, and the anchoring members having a substantially oval cross-section.

Hayashi teaches a device with anchoring members 40 being attached to the inner surface of the wall of the deployment element 50 inner lumen. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg by attaching the anchoring members to the inner surface of the wall of the deployment element inner lumen as taught old and well known by Hayashi as an alternative design of connection between two segments. Since Applicant's disclosure lacks criticality for attaching the anchoring members within the wall of the deployment means, the Examiner has considered this feature as a mere modification or variation from Goldberg (over the outer surface of the deployment means) and Hayashi (in the inside surface of the deployment means) connections. Also, the oval cross-section is an obvious variation from the circular cross-section.

12. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg in view of Hayashi as applied to claim 28 above, and further in view of Abrams.

Goldberg/Hayashi discloses the invention substantially as claimed as discussed above. However, Goldberg/Hayashi fails to disclose the anchoring members comprising a pseudo elastic material such as nickel titanium alloy.

Abrams teaches a catheter apparatus comprising control wires having curved feet made of nitinol, which is a pseudo elastic material for anchoring purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg in view of Hayashi by providing the anchoring members with the materials of Abrams as taught old and well known in the art for anchoring purposes.

13. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al in view of Hayashi as applied to claim 28 above, and further in view of Lefebvre.

Goldberg/Hayashi discloses the invention substantially as claimed as discussed supra. However, Goldberg/Hayashi fails disclose the anchoring members having a substantially flat top portion.

Lefebvre teaches a filter (anchoring member) having a substantially flat top portion for anchoring purposes in a blood vessel (see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg/Hayashi by providing the anchoring members with the substantially flat top portion of Lefebvre to anchor the anchoring members to the passageway of a blood vessel and as an obvious design alternative.

14. Claims 41- 43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi in view of Abrams and Hayman et al.

Hayashi discloses the invention substantially as claimed as discussed above. However, Hayashi fails to disclose the anchoring members being of a pseudo elastic material such as nickel titanium alloy or made of spring steel, or the anchoring members having a substantially oval cross-section.

Abrams teaches a catheter apparatus having control wires having curved feet made of nitinol, which is a pseudo elastic material, and Hayman teaches an anchor 19 having arms 21 made of spring steel for anchoring purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Hayashi by providing the anchoring members with the materials of Abrams and Hayman as taught old and well known in the art for anchoring purposes. Also, the oval cross-section is an obvious variation from the circular-cross section.

15. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi in view of Lefebvre.

Hayashi discloses the invention substantially as claimed as discussed above. However, Hayashi fails to disclose the anchoring members having a substantially flat top portion.

Lefebvre teaches a filter (anchoring member) having a substantially flat top portion for anchoring purposes in a blood vessel (see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Hayashi by providing the anchoring members with the substantially flat top portion of Lefebvre to anchor the anchoring members to the passageway of a blood vessel and as an obvious design alternative.

Response to Arguments

16. Applicant's arguments filed May 28, 2003 have been fully considered but they are not persuasive.

17. In regards to Applicants arguments that Cathcart does not teach or suggest "a plurality of resilient anchoring members attached to the distal end of the inner lumen.", this is not found persuasive. The examiner has stated that the word "attached" has several definitions such as to join or connect, to bring into an association, to assign temporarily. The word attached does not particularly means **permanently** bonded or affixed to an element. The examiner suggests the use of **permanently attached** in order to overcome the reference. Furthermore, Applicants argument that Cathcart does not teach or suggest "each anchoring member [is] reversibly moveable by deployment element between a first position and a second position" is not persuasive. In Cathcart, figure 1 shows that the deployment

element 17 is in a first position (at least a portion of each anchoring member is retracted within the outer lumen), and a second position in figure 5 (at least a portion of each anchoring member is deployed exteriorly to the outer lumen so as to engage the inner surface of a passageway. Therefore, Cathcart discloses the first and second position as claimed. Further, the independent claims do not set forth a means for pulling the deployable device back inside of the catheter. Also, applicants state that their invention is for anchoring a catheter within a passageway, however, it is not clear from the claims how the tubular element (catheter) is anchored to the passageway. It seems that the deployment element and the anchoring members limit the axial movement of the tubular element rather than anchoring.

18. In regards to applicant's arguments that Goldberg does not teach an inner lumen having a bore extending completely through the inner lumen, the examiner directs applicant's attention to Col. 8 lines 23-66. Lumen 62 extends from proximal (out of the patient) to distal end (inside the body).

19. In regards to applicant's arguments about Hayashi's device, it has all the elements as claimed and is capable of temporarily anchoring a passageway.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Selmon et al, and Palestrant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

June 25, 2003

Cris L. Rodriguez
Examiner
Art Unit 3763

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